Human Subject Research (Clinical Research) Concerns/Issues

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Overview

- Clinical Research Definition
- IRB role/regulations
- NIH policy
  - Inclusion of Women/Minorities/Children
  - Data and Safety Monitoring
- Information Sources

NIH Definition of Clinical Research

(1) Patient-oriented research.

Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual.

NIH Definition of Clinical Research (Con't)

Patient-oriented research includes:

a) mechanisms of human disease,

b) therapeutic interventions,

c) clinical trials, and

d development of new technologies

NIH Definition of Clinical Research Con't

(2) Epidemiologic and behavioral studies;

(3) Outcomes research and health services research.

Bottom Line: It is clinical research if:

- Direct Interaction with living individuals

or

- Access to Readily Identifiable Data (name, address birthdate, SSN,unique code, etc)

Role of the IRB

Federal Policy for the Protection of Human Subjects (45 CFR 46)

http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

Applies to all research involving human subjects unless granted an exemption

Office of Human Research Protection Decision Tree

http://ohrp.osophs.dhhs.gov/humansubjects/guidance/decisioncharts.htm

NIH Policies Regarding Studies Involving Human Participants

Required Education in the Protection of Human Research Participants
http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html

Inclusion of Women and Minorities
http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html

Inclusion of Children
http://grants1.nih.gov/grants/guide/notice-files/not98-024.html

Data and Safety Monitoring Plans
http://grants1.nih.gov/grants/guide/notice-files/not98-084.html
http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

NIH Policy on Inclusion of Women & Minorities in Clinical Research

- Why does NIH have this policy?
  - Mandated by Congress, 1993 PL 103-43
  - Ethical principal of justice and importance of balancing research burdens and benefits

Public Law PL 103-43

- Women and Minorities must be included in all clinical research studies
- Women and Minorities must be included in Phase III clinical trials in numbers adequate for valid analysis
- Cost is NOT allowed as an acceptable reason for exclusion
- NIH to support outreach efforts to recruit and retain women, minorities, and their subpopulations in clinical studies

Inclusion of Children

- Defined as individual under 21 years
- Rationale for selecting or excluding specific age range of children
- Must include expertise of investigators in dealing with children in the age range
- Check state law regarding age of consent (or assent)

Data and Safety Monitoring of Clinical Studies

- Should be commensurate with the risk
- Establishes the overall framework for data and safety monitoring
- Description of entity responsible for monitoring (who, how, what, by whom)
- Adverse event reporting to IRB, NIH, FDA, OBA
- Multicenter clinical trials need a DSMB
- http://www.niddk.nih.gov/patient/datasafetymonitor.htm

Resources and Getting Help

- PHS 398 Instructions

http://grants1.nih.gov/grants/funding/phs398/phs398.html

- CONTACT PROGRAM STAFF!